REMARKS

In reply to the Office Action mailed November 2, 2006, Applicants amended claim 1. Claims 1-3, 6-11, 21, 26-28, and 30-33 are pending and under examination. Please consider the following remarks.

Claims 1-3, 6-11, 21, 26-28, and 30-33 have been objected to under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner objected to the phrase "and optical isomers, racemates, and tautomers thereof and pharmaceutically acceptable salts," suggesting that the word "and" should be replaced with the word "or." Applicants have amended claim 1 to replace "and" with "or" as suggested by the Examiner. Applicants submit that the pending claims are sufficiently definite and request that the corresponding rejection be withdrawn.

Claims 1-3, 6-11, 21, 26-28, and 30-33 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. All of the pending independent claims recite a compound or a solvate thereof, which are recited either generically, for example, as provided in claim 1, or specifically, for example, as provided in claim 30. The Examiner asserts that the specification does not reasonably provide enablement for making and using solvates of formula I. Applicants disagree.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. (See United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).) The Federal circuit has provided a list of factors to be considered in determining enablement in In re Wands, which are as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. These factors are discussed below as they relate to the pending claims, but are not necessarily discussed in the same order as above.

The pending claims are directed to thiophene containing compounds having formula (I). The claims further recite optical isomers, racemates, tautomers and pharmaceutically acceptable salts and solvates of formula (I). In describing the breadth of the claims, the Examiner notes that the term "solvates" covers various forms of the same compound at different proportions of solvents, and is therefore unduly broad. While Applicants agree with the Examiner's characterization of the term solvates, Applicants disagree with the Examiner's conclusion that the term solvates renders the claims unduly broad. Applicants have provided numerous examples of compounds within the claimed formula, including an example of a solvate of a specific compound.[1] In Example 3 of the specification the solvate was prepared using a trivial procedure, i.e., a recrystallization of product from a solvent mixture.[2]

A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Applicants submit that the skill in the art is high, e.g., a chemist with a Ph.D. or a chemist with several years of practical training. Moreover, solvates are well known in the art and can be made by a skilled artisan using routine experimental procedures. For example, recrystallization procedures are routinely used as a purification step in the synthesis of a product such as a pharmaceutically acceptable product. This type of routine experimentation is exemplified in the specification with the trivial recrystallization procedure described in Example 3. As demonstrated in Example 3, a solvate often contains one or more solvents used in the recrystallization step. Accordingly, one skilled in the art would reasonably expect that a change in solvent would result in a change in solvated form of the compound. Because solvates can be made and modified using procedures well known in the art, and Applicants submit that the specification need not teach these procedures to provide an enabling disclosure.

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[1] It appears the Examiner has overlooked the example of a solvate as provided in Applicants' specification. See Office Action, paragraph bridging pages 3 and 4.

[2] The solvate has a 1:1 stoichiometry of a compound of formula (I) with dimethylsulphoxide, and is produced using a routine recrystallization procedure with a methanol and dimethylsulphoxide solvent system.

Although the Examiner appears to concur with Applicants' view that solvates are known in the art, the Examiner asserts that "the process for selecting a particular solvent to make a solvate is not standard for all drugs." (See Office Action page 4, first full paragraph.) Applicants submit that a standard process for selecting a particular solvent is not required as long as the solvent could be selected using "routine experimentation." "A considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). In addition to the fact that the type of experimentation required to produce a solvate is routine, Applicants submit that the specification provides ample guidance as to the selection of a solvent. For example, the specification refers to pharmaceutically acceptable solvates, which certainly provides guidance to the skilled artisan when selecting a solvent for the claimed compounds. Applicants submit that those potential solvents from which a skilled artisan would select would be limited to those appropriate for pharmaceutical use, for example, those lacking unacceptable levels of toxicity and excluding those solvents known to be carcinogens.

A balancing of the factors above leads to the conclusion that the pending claims are enabled because a skilled artisan could practice the full scope of the invention, including making and using solvates of formula (I), without undue experimentation. Applicants therefore request that the corresponding rejection be withdrawn and that the application be placed in condition for allowance.

The required amount of $450 for the Petition for Extension of Time fee is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 06275-233001.

Respectfully submitted,

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